K092909

SYNTHES®

3.0 **510(k) Summary**

JAN 11 2010

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Contact: Sheri L. Musgnung
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940
FAX (484) 356-9682

Device Name: Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws (SCFE)

Classification: Class II, §888.3040 – Smooth or threaded metallic bone fixation fastener

Predicate Device: Synthes 6.5 mm Cannulated Screws
Synthes Washers

Device Description: The Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws (SCFE) have a cannulated shaft, are self-tapping with a cancellous thread that can be guided into position via a 2.8 mm guide wire, and range in overall lengths from 45 mm – 130 mm, and have 10 mm and 20 mm thread lengths. Oval washers of 1 mm and 2 mm are also available to use with the screws for precise depth placement in bone. The screws and washers are available in stainless steel.

Intended Use: The Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws are intended for fracture fixation of large bones and large bone fragments including femoral neck fractures; slipped capital femoral epiphyses; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodeses.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Synthes USA, Inc.
% Ms. Sheri L. Musgnung
1301 Goshen Parkway
West Chester, Pennsylvania 19380

JAN 11 2010

Re: K092909
Trade/Device Name: Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws (SCFE)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 23, 2009
Received: December 24, 2009

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K092909

Device Name: Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws (SCFE)

Indications for Use:

The Synthes 7.3 mm Cannulated Slipped Capital Femoral Epiphysis Screws are intended for fracture fixation of large bones and large bone fragments including femoral neck fractures; slipped capital femoral epiphyses; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodeses.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092909